

Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 10/626,142

Confirmation No.: 9324

Filed: 24 July 2003

For: DENTAL WHITENING COMPOSITIONS AND METHODS

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Remarks

The Office Action mailed 13 October 2006 has been received and reviewed. No claims having been added, amended, or canceled, the pending claims are claims 1-80. Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-6, 8-12, 14-20, 22-27, 29, 46-49, and 57-72 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that "fluoride releasing groups" are not adequately described by the specification. Reconsideration of this rejection is respectfully requested in view of the following remarks.

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." M.P.E.P. §2163(I). "An applicant may . . . show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." M.P.E.P. §2163(II)(A)(3)(a).

Applicants respectfully submit that the remarks presented on pages 2 to 4 of the Response submitted 25 May 2006, which are incorporated herein by reference, are sufficient to overcome the present rejection. Nonetheless, the Examiner responded by noting that "[t]he monomers on page 10 which Applicant argues are described as fluoride releasing groups are actually described in the Specification as the polarizable side group" (pages 5 to 6 of the Office Action mailed 13 October 2006). Because nothing precludes a polarizable side group from being a fluoride

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releasing group, Applicants respectfully submit that the Examiner's remarks are inapposite the present rejection.

Further, Applicants respectfully submit that it would be clear to one of skill in the art that salts that include, for example, fluoride anions and/or tetrafluoroborate anions can be fluoride releasing groups. *See, for example*, the present specification at, for example, page 11, line 21 (reciting that "[s]uitable fluoride releasing groups include fluoride salts") and page 11, lines 24-25 (reciting that "[a] preferred fluoride releasing group includes tetrafluoroborate anions"). Moreover, Applicants respectfully submit that such fluoride releasing groups are well known to one of skill in the art.

"Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification." M.P.E.P. §2163(II)(A)(2). "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. . . . If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." M.P.E.P. §2163(II)(A)(3)(a). "A patent need not teach, and *preferably omits*, what is well known in the art." M.P.E.P. §2163.01 (emphasis added).

Applicants respectfully assert that fluoride releasing groups are well known to one of skill in the art. *See, for example*, U.S. Patent No. 4,871,786 (Aasen et al.), which "relates to compositions which are capable of releasing fluoride ions" (column 1, lines 5-6). Applicants note that the assertion that fluoride releasing groups are well known in the art is consistent with the Examiner's position on the record. *See, for example*, page 7 of the Office Action mailed 13 October 2006 (stating that EP 0363095 A2 discloses "tetrafluoroborate ions as fluoride releasing groups"); and page 8 of the Office Action mailed 13 October 2006 (stating that "[t]he EP 0363095 reference also teaches fluoride releasing groups such as tetramethylammonium

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tetrafluoroborate . . . as well as a fluoride source that may be polymerizable with a polymerizable monomer").

Because fluoride releasing groups are well known to one of skill in the art, Applicants respectfully submit that such fluoride releasing groups need not be described in detail, and preferably are not described in detail, in the instant specification. For at least this reason, Applicants respectfully submit that the present claims are adequately supported by the specification to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

#### Rejection under 35 U.S.C. §102

The Examiner rejected claims 1-3, 23-25, 30-32, 46, 49-50, 53-56, and 65-72 under 35 U.S.C. §102(b) as being anticipated by EP 0363095 A2 to Minnesota Mining and Manufacturing Company. This rejection is respectfully traversed.

Applicants respectfully submit that the remarks presented on pages 8 to 10 of the Response submitted 25 May 2006, which are incorporated herein by reference, are sufficient to overcome the present rejection. Nonetheless, the Examiner responded by noting that "the EP 0363095 reference teaches peroxides, which are tooth whiteners, which after application to the tooth are exposed to light" (page 9 of the Office Action mailed 13 October 2006). While EP 0363095 A2 clearly discloses *the combination of a monomer with a peroxide*, Applicants earnestly disagree with any inference by the Examiner that EP 063095 A2 discloses *the combination of a polymer with a peroxide*.

Specifically, EP 0363095 A2 recites the following:

Typically the compositions of the invention will be capable of free radical polymerization. Accordingly, they will comprise a polymerization initiation system such as an organic peroxide either alone or preferably in combination with a suitable amine, sulfide,

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thiol, phosphine or other such compound capable of producing radicals via reaction with the peroxide. Alternatively, the compositions may comprise a photoinitiation system such as a ketone or an alpha diketone, either alone or preferably in combination with a suitable amine, peroxide, sulfide, thiol, phosphine or other such compound capable of being sensitized by or otherwise reacting with the carbonyl compound to initiate free radical polymerization of the composition upon exposure to light. (Page 7, lines 47-54).

In brief, EP 0363095 A2 discloses the use of *peroxides, which can decompose to produce radicals, in an initiation system for polymerizing polymerizable monomers*. Further, Applicants were unable to locate, in EP 0363095 A2, any disclosure of the combination of *a polymer with a peroxide*. Moreover, the Examiner has not provided any basis in fact and/or technical reasoning that would reasonably support a hypothetical assertion that a *polymer* resulting from the polymerization of the polymerizable monomers with a peroxide-containing initiation system (i.e., in which peroxides decompose to produce radicals) as described in EP 0363095 A2 would *necessarily* include a *peroxide*. Thus, EP 0363095 A2 fails to disclose *the combination of a polymer with a peroxide*.

For at least this reason, Applicants respectfully submit that claims 1-3, 23-25, 30-32, 46, 49-50, 53-56, and 65-72 are not anticipated by EP 0363095 A2. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102 are respectfully requested.

**Rejections under 35 U.S.C. §103**

The Examiner rejected claims 1-80 under 35 U.S.C. §103(a) as being unpatentable over EP 0363095 A2 to Minnesota Mining and Manufacturing Company and further in view of Huang et al. (U.S. Patent No. 6,083,421). Applicants respectfully traverse the rejection.

The deficiencies of EP 0363095 A2 as applied to claims 1-3, 23-25, 30-32, 46, 49-50, 53-56, and 65-72 have been discussed herein above in the traverse of the rejection under 35 U.S.C. §102. Claims 4-7, 26-29, and 33-36 depend therefrom. In brief, EP 0363095 A2 fails to disclose

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or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claims 1-7, 23-36, 46, 49-50, 53-56, and 65-72.

Claims 8-14 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *greater than 10% by weight of a tooth whitening agent*, based on the total weight of the dental whitening composition, and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a fluoride releasing group. Claim 47 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that include a dental whitening composition as recited in claim 8; and claims 57-60 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 8.

Claims 15-22 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and *a polymer* that includes a repeating unit including a polar or polarizable group and a repeating unit including a fluoride releasing group, with the proviso that the dental whitening composition does not include hydrogen peroxide. Claim 48 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 15; and claims 61-64 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 15.

Claims 37-40 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *greater than 10% by weight of a tooth whitening agent*, based on the total weight of the dental whitening composition, and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof. Claim 51 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 37; and claims 73-76 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 37.

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Claims 41-45 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof, with the proviso that the dental whitening composition does not include hydrogen peroxide. Claim 52 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 41; and claims 77-80 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 41.

Applicants respectfully submit, for reasons similar to those discussed herein above in the traverse of the rejection under 35 U.S.C. §102, that EP 0363095 A2 fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claims 1-80.

Further, Applicants respectfully submit that Huang et al. fails to cure the deficiencies of EP 0363095 A2. Specifically, Huang et al. "relates to a tooth-whitening varnish composition, comprising 6-20% of carbamide peroxide, 2-9% of film forming agent and 77-88% of volatile organic solvent, based on the total weight of the composition. The volatile organic solvent is selected from ether, ethylacetate, ethyl alcohol, or acetone. The film forming agent is artificial or natural material selected from cellulose, polyvinyl, butyral, coumarone resin or shellac." (Abstract). However, Huang et al. fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claims 1-80.

Thus, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability of claims 1-80 over EP 0363095 A2 in view of Huang et al.

The Examiner rejected claim 35 under 35 U.S.C. §103(a) as being unpatentable over EP 0363095 A2 to Minnesota Mining and Manufacturing Company as applied to claims 1-80 above taken with Lakshmanan (U.S. Patent No. 4,018,732). Applicants respectfully traverse the rejection.

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Claim 35 depends from claim 30. The deficiencies of EP 0363095 A2 as applied to claim 30 have been discussed herein above in the traverse of the rejection under 35 U.S.C. §102. In brief, EP 0363095 A2 fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claim 30. Applicants respectfully submit that Lakshmanan provides nothing to correct the deficiencies of EP 0363095 A2. Thus, for at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of claim 35 over EP 0363095 A2 in view of Lakshmanan.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

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It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21<sup>st</sup> day of December, 2006, at 11:59 a.m. (Central Time).

By: Name: Rachel Engelhardt